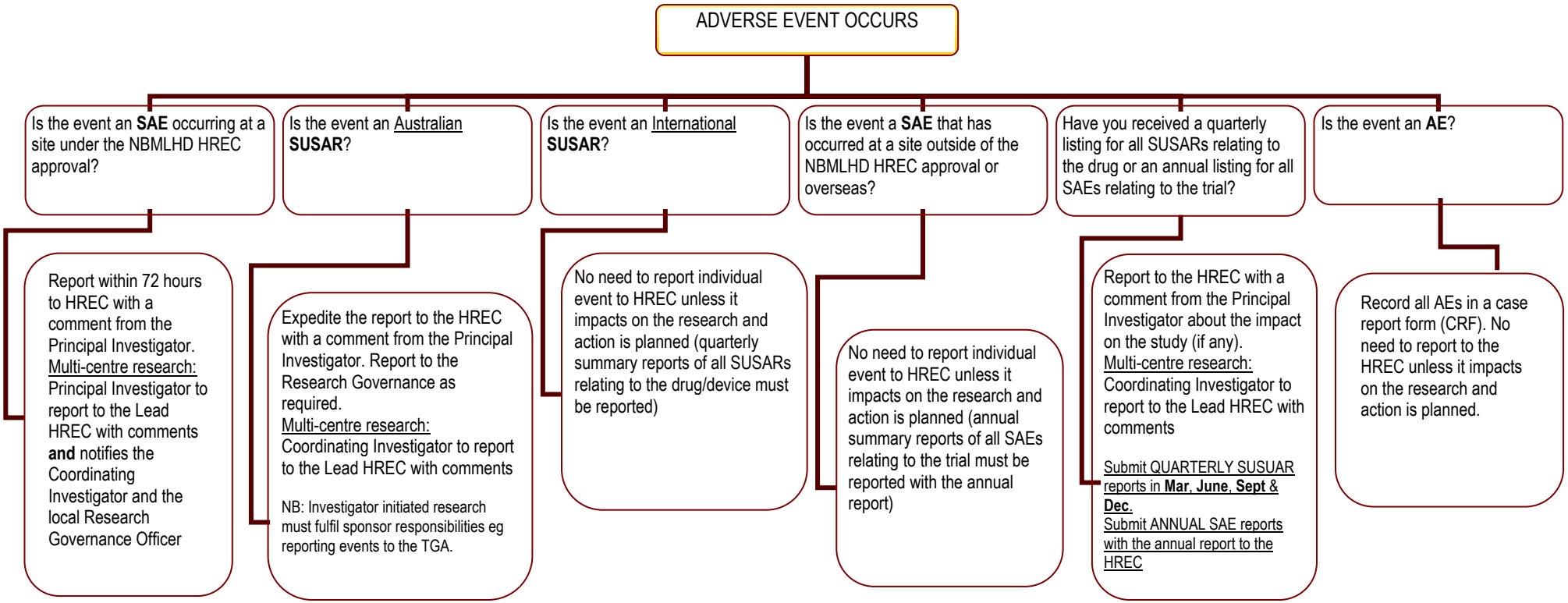
Adverse Event Reporting to the NBMLHD HREC for Clinical Trials

For Human Research Ethics Committees to be able to protect the safety of clinical trial participants, sufficient information about adverse events must be provided in context.
Supplying this information is a condition of ethical approval.

Step 1: Is the event an SAE? **Step 2:** Is it unexpected? **Step 3:** Is it related to the drug/device? **If yes to all 3 = SUSAR**

SUSAR - Serious, Unexpected, Suspected Adverse Reaction	An SAE which is **probably** related to the drug and is **unexpected.** This assessment is made after the data is un-blinded (by the Data Safety Monitoring Board - DSMB) to judge causality.
SAE - Serious Adverse Event	An event resulting in: ❖ Hospitalisation/prolongation of hospitalisation ❖ Death/congenital abnormality ❖ Life threatening/medically important ❖ Persistent disability
AE - Adverse Event	Any untoward event that does not necessarily have a causal relationship with the treatment. These may be expected (defined in the Investigator Brochure)
Unexpected Adverse Event	Not defined in the current Investigator Brochure / Product Information

ALL REPORTS MUST BE SUBMITTED USING THE ADVERSE EVENT REPORTING FORMS AVAILABLE FROM THE RESEARCH OFFICE (individual event or summary of events)



References: NHMRC HREC Alert No1, 18 April 2007; NSW Health Model for Single Ethical and Scientific Review of Multi-centre Research, SOP 23.3 (August 2007)
Adopted from St Vincent's HREC